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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,785	06/27/2005	Aladar A. Szalay	3800002.00055 / 4804US	7336
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K&L Gates LLP 3580 Carmel Mountain Road Suite 200 San Diego, CA 92130				
EXAMINER				
BURKHART, MICHAEL D				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
07/20/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/516,785

**Applicant(s)**

SZALAY ET AL.

**Examiner**

Michael Burkhardt

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 9, 12-16, 18 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 13 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 12, 18 and 22 is/are rejected.
- 7) ☒ Claim(s) 6, 14, 16 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/13/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt and entry of the amendment dated 4/27/2010 is acknowledged. After entry of the amendment, claims 1-6, 9, 12-16, 18 and 21-23 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 102***

Claims 1, 2, 9, 12, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu et al (1994, Zhonghua Wai Ke Za Zhi, cited by applicants). **This rejection is maintained for reasons made of record in the Office Action dated 4/1/2009, 10/27/2009, and for reasons set forth below.**

The claims have been amended in a largely semantic nature. The addition of a limitation of "identifying a subject to be tested..." is a mental process performed by the skilled artisan that was an inherent feature of the claims prior to amendment, particularly in light of the following method step of "systemically administering to the subject ...a bacterium." Prior to administration, Fu et al had to "identify", or choose, those rats that were to be used in the experiments that followed.

The claims have been further amended to recite that an "imaging" step is performed to detect accumulation of the bacteria, rather than the previous recitation the method step "to detect the accumulation of the bacterium at or in the wounded tissue." An imaging step implies a process of visualizing the bacteria rather than other detection steps such as culture or PCR. Fu et

al teach visualization of fluorescently labeled bacteria for reasons of record (see page 3 of the English translation).

***Response to Arguments***

Applicant's arguments filed 4/27/2010 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Fu et al do not disclose a step of detecting wounds or inflamed tissues; 2) Fu et al do not introduce bacteria into a subject in which inflamed or wounded tissue is to be detected; 3) Fu et al are concerned with studying infection following burns, not detection of wounds or inflamed tissue; 4) because Fu et al are concerned with bacterial trafficking, it does not disclose the method step of "identifying a subject.."; 5) Fu et al do not teach a step of systemically administering a bacterium, but rather use an injection of bacteria through a gastric catheter; 6) the instant methods do not include a step of burning animals, as found in Fu et al; 7), the order of events in Fu et al is reversed compared to the instant claims, i.e. Fu et al administers the bacteria, then burns the animals;

Regarding 1), this assertion is false on its face. Fu et al clearly detected the administered bacteria in burn wounds. That Fu et al may have been studying bacterial trafficking is irrelevant, this is not a 35 USC 103 rejection.

Regarding 2) and 3), this assertion, again, is false on its face. Applicants present no reasoning or logic as to why a burn is not to be considered "a wounded or inflamed tissue." To detect the administered bacteria in such tissue was the entire point of Fu et al. The fact remains that Fu et al teach all the instant claim limitations, even though the purpose of Fu et al may have differed from the instant claims. This does not mitigate against a 35 USC 102 rejection.

Regarding 4), this issue is addressed above.

Regarding 5), the administration step of Fu et al is considered systemic for reason of record, i.e. the administered bacteria were found throughout the body of the subject animals. Applicants provide no limiting definition for a "systemic administration", and none is found in the instant specification. Thus, the claims are not as limited, as applicant insist, to IV, IM or oral administration. Further, it is unclear how oral administration could be considered systemic and gastric administration not, as both involve adsorption of the bacteria through the GI tract.

Regarding 6), the instant claims do not specifically exclude detecting burns, or a step of burning animals (as reprehensible as that step may be). Due to the broad wording of "wounded or inflamed tissue", burns are considered to be included within the scope of the claims, no matter how such burns may have arisen.

Regarding 7), a reading of the claims reveals that there is no set limitation as to when the wounded or inflamed tissue must be present relative to the administration of the bacteria. The claims recite "a subject to be tested", which implies wounds in the present or perhaps in the future.

#### ***Allowable Subject Matter***

Claims 6, 14, 16 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 23 is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/  
Primary Examiner, Art Unit 1633